



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

DU PLESSIS

Atty. Ref.: 511-70

Serial No. 10/557,192

Group: 1616; Conf. No.
1113

Filed: July 31, 2006

Examiner: Arnold, Ernst V.

For: PREPARATION OF AN OSTEOINDUCTIVE AGENT

* * * * *

November 30, 2009

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RULE 132 DECLARATION OF TJAART ANDRIES DU PLESSIS

I, Tjaart Andries Du Plessis, declares and states as follows:

1. I am the named inventor in the above-identified application. I hold a PhD in Radiation Chemistry and acts as an expert advisor to the International Atomic Energy Agency, and have 45 years' experience in the field of radiation processing.

2. I have reviewed the Office Action issued by the U.S. Patent Office in my application on July 28, 2009.

3. I have also reviewed U.S. Patent No. 6,610,810 issued to Phillips *et al.* and cited by the Examiner in his rejection of my application the July 28, 2009 Office Action. I am the Tjaart Andries Du Plessis named as one of the co-inventors in the Phillips patent.

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DU PLESSIS

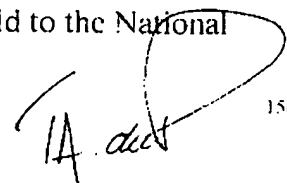
Serial No. 10/557,192

4. My invention is directed to, among other things, a cost-effective, sterile and user friendly kit for medical professionals in the orthopedic environment. The kit is used to prepare and dispense an osteoinductive agent, which includes a plurality of biocompatible biopolymers that are first mixed together before being subjected to a source of ionising radiation.

5. While it is known that radiation is useful for sterilizing products, there are advantages to first mixing the biocompatible biopolymers used in my invention and then radiating the product. These advantages include (i) enhanced cross-linking of the biopolymers, (ii) a decrease in production time and costs, eliminating the steps of first radiating the products separately, and thereafter, mixing them and radiating the product again before packaging, and (iii) reducing the chances for contamination.

6. Radiation is a cold process and is, therefore, especially applicable to plastics disposables, as it will not distort the plastic. Therefore, to ensure sterility of the final product of my invention, the entire kit (the modified naturally occurring biocompatible biopolymer and the primary, secondary and tertiary containers) is sealed in plastic and radiated again to ensure that the product is sterile and ready for use by medical professionals in the orthopedic sterile environment.

7. Since May of 2003, 5250 units of my kit have been sold to the National

A handwritten signature in black ink, appearing to read "A. de P.", is written over the word "National" in the text of paragraph 7.



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Patent Assignment Abstract of Title

**NOTE: Results display only for issued patents and published applications.
For pending or abandoned applications please consult USPTO staff.**

Total Assignments: 1

Patent #: NONE

Issue Dt:

Application #: 10557192

Filing Dt: 07/31/2006

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Inventor: Tjaart Andries Du Plessis

Title: Preparation of an osteoinductive agent

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Pages: 2

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

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Exec Dt: 11/29/2005

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Total Assignments: 2

Patent #: [6610810](#)

Issue Dt: 08/26/2003

Application #: 09805385

Filing Dt: 03/13/2001

Publication #: [20030027883](#)

Pub Dt: 02/06/2003

Inventors: Glyn Owen Phillips, Tiaart Andries Du Plessis, Saphwan Al-Assaf et al

Title: BIOPOLYMERS OBTAINED BY SOLID STATE IRRADIATION IN AN UNSATURATED GASEOUS ATMOSPHERE

Assignment: 1

Reel/Frame: [014718/0251](#)

Recorded: 11/24/2003

Pages: 13

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

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Exec Dt: 08/19/2003

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Exec Dt: 08/13/2003

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Exec Dt: 08/18/2003

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Exec Dt: 08/19/2003

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Assignment: 2

Reel/Frame: [016153/0584](#)

Recorded: 01/21/2005

Pages: 3

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